



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2017-0559; FRL-9978-62]

### Final Strategic Plan to Promote the Development and Implementation of Alternative Test Methods Supporting the Toxic Substances Control Act (TSCA); Notice of Availability

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** As required by TSCA, which was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act in June 2016, EPA is announcing the availability of a document entitled: *Strategic Plan to Promote the Development and Implementation of Alternative Test Methods Supporting the Toxic Substances Control Act (TSCA)*. EPA is also making available a response to comments document that addresses comments received on the draft Strategic Plan.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Louis Scarano, Risk Assessment Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 202-564-2851, email address: [scarano.louis@epa.gov](mailto:scarano.louis@epa.gov). In addition, progress on this activity will be periodically updated at the following page on the OPPT website at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca>.

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

## SUPPLEMENTARY INFORMATION:

### I. General Information

#### A. Does this Action Apply to Me?

You may be potentially affected by this action if you are required to conduct testing of chemical substances under the Toxic Substances Control Act (TSCA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Basic Chemical Manufacturers (NAICS code 3251);
- Resin, Synthetic Rubber, and Artificial Synthetic Fibers and Filament Manufacturers (NAICS code 3252);

- Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturers (NAICS code 3255);
- Paint, Coating, and Adhesive Manufacturers (NAICS code 3255);
- Other Chemical Product and Preparation Manufacturers (NAICS code 3259); and Petroleum Refineries (NAICS code 32411);
- Animal Welfare Groups;
- Environmental non-governmental organizations;
- Toxicity testing laboratories (contract labs);
- Academic/non-profit groups involved in developing and using alternative toxicity test methods.

*B. How Can I Get Copies of this Document and Other Related Information?*

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2017-0559, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

*C. What is the Agency's Authority for this Action?*

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act amended TSCA (15 U.S.C. 2601 *et seq.*), the nation's primary chemicals management law. Along with new requirements and deadlines for actions related to the regulation of new and existing chemicals in the U.S., the new law includes changes to TSCA section 4 (*Testing of Chemical Substances and Mixtures*). Specifically, a new TSCA section 4(h) has been added entitled *Reduction of Testing on Vertebrates*. TSCA section 4(h)(2)(A) states that EPA shall "..., not later than 2 years after June 22, 2016, develop a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing and provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment...". (15 U.S.C. 2603(h)(2)(A)).

*D. What Action is the Agency Taking?*

In fulfillment of the requirements in TSCA section 4(h)(2)(A), EPA has prepared a final Strategic Plan to "promote the development and implementation of alternative test methods and strategies to reduce, refine or replace vertebrate animal testing and provide information of

equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment of chemical substances or mixtures...". The Strategic Plan is being made available in both the docket and on the EPA website.

In addition, making available a response to comments document that addresses comments on the draft Strategic Plan received through May 11, 2018. The response to comment document is available in the docket. (<http://www.regulations.gov>; docket ID number HQ-OPPT-2017-0559)

## **II. Background**

OPPT hosted a public meeting on November 2, 2017, in which a conceptual approach to this final Strategic Plan was presented. Meeting materials and public comments received through January 10, 2018, can be found in the docket. (<http://www.regulations.gov>; docket ID number HQ-OPPT-2017-0559).

A draft Strategic Plan was published on March 12, 2018, along with a response to comments document that addressed the comments received through January 10, 2018. OPPT hosted a second public meeting on April 10, 2018, to receive input from the public on the draft Strategic Plan. A docket was made available with the meeting materials and allowed for comments to be received through May 11, 2018 (<http://www.regulations.gov>; docket ID number HQ-OPPT-2017-0559).

**Authority:** 15 U.S.C. 2601 *et seq.*

Dated: June 21, 2018.

**E. Scott Pruitt,**

*Administrator.*

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